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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,120	12/07/2001	Yoshihiro Kurano	0760-0299P	2911

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EXAMINER

SWARTZ, RODNEY P

ART UNIT PAPER NUMBER

1645

DATE MAILED: 08/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,120	KURANO ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7-16 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 is/are allowed.
- 6) ☒ Claim(s) 1,2,4,7-16,18-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Applicants' Response to Office Action, received 26May2004, is acknowledged. Claims 3, 6, and 17 have been cancelled. Claims 1, 2, 4, 8-12, and 14-16 have been amended. New claims 18-20 have been added.
2. Claims 1, 2, 4, 5, 7-16, and 18-20 are pending and under consideration.

Rejections/Objections Moot/Withdrawn

3. The rejection of claim 6 under 35 U.S.C. 112, second paragraph, indefiniteness, is moot in light of the cancellation of the claim.
 4. The rejection of claims 3 and 6 under 35 U.S.C. 112, second paragraph, indefiniteness, is moot in light of the cancellation of the claim.
 5. The rejection of claim 3 under 35 U.S.C. 112, second paragraph, indefiniteness, is moot in light of the cancellation of the claim.
 6. The rejection of claims 3 and 6 under 35 U.S.C. 102(b) as being anticipated by Prusiner et al (U.S. Pat. No. 5,846,533) is moot in light of the cancellation of the claim.
 7. The objection to claim 4 is withdrawn in light of the claim amendment.
 8. The objection to claim 10 is withdrawn in light of the claim amendment.
 9. The rejection of claim 9 under 35 U.S.C. 112, second paragraph, indefiniteness, is withdrawn in light of the claim amendment.
 10. The rejection of claim 8 under 35 U.S.C. 112, second paragraph, indefiniteness, is withdrawn in light of the claim amendment.
- The rejection of claim 14 under 35 U.S.C. 112, second paragraph, indefiniteness, is withdrawn in light of the claim amendment.

11. The rejection of claims 1, 2, 4, 5, and 7-16 under 35 U.S.C. 112, second paragraph, indefiniteness, is withdrawn in light of the claim amendments.

Rejections Maintained

12. The rejection of claim 11 under 35 U.S.C. 112, second paragraph, indefiniteness, is maintained and now includes newly added claim 19.

The amendment of claim 11 now recites "The process according to claim 10 wherein peptide is immobilized on a carrier." The recitation does not restrict "peptide" to that recited in claim 10, but merely recites that "peptide immobilized on a carrier". It is recommended that the claim be amended to recite "said peptide is immobilized on a carrier".

Newly added claim 19 depends from claim 11, but does not correct the indefiniteness. Newly added claim 19 would have been included in the original rejection.

13. The rejection of claims 12-15 under 35 U.S.C. 112, second paragraph, indefiniteness, is maintained and now includes newly added claim 19.

Newly amended claim 12 now recites "The process according to claim 10 wherein said immunogen comprises at least two types of said peptide, said peptides further being immobilized on a carrier." Claim 10 only recites one type of peptide which consists essentially of a plurality of regions in abnormal type prion. It is unclear what is meant by "at least two types of said peptide".

Newly added claim 19 depends from claim 12, but does not correct the indefiniteness. Newly added claim 19 would have been included in the original rejection.

14. The rejection of claims 1, 2, 7, and 8 under 35 U.S.C. 102(b) as being anticipated by Prusiner et al (U.S. Pat. No. 5,846,533) is maintained and now includes newly added claims 18 and 20.

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Applicants argue that the monoclonal antibody of Prusiner et al requires that the antiabnormal type prion monoclonal antibody originate from an animal immunized with an immunogen including a peptide consisting essentially of a plurality of regions in said abnormal type prion. Thus, Prusiner et al fails to suggest or disclose such a monoclonal antibody and therefore, there exists no anticipation.

The examiner has considered applicants' argument, but does not find it persuasive. The rejection is maintained for the reasons put forth in the original rejection. The claims are drawn to a monoclonal antibody which binds with abnormal type prion but does not substantially bind with normal type prion. In the absence of evidence to the contrary, the process by which the antibody is produced does not impart any criticality to the product's binding characteristics. Thus, the monoclonal antibody of Prusiner et al does anticipate applicants' antibody.

Newly added claims 18 and 20 depend from claim 1 and are also drawn solely to a monoclonal antibody which binds to an antiabnormal type prion. Newly added claims 18 and 20 would have been included in the original rejection

15. The rejection of claim 9 under 35 U.S.C. 103(a) as being unpatentable over Prusiner et al (U.S. Pat. No. 5,846,533) is maintained.

Applicants argue that the monoclonal antibody of Prusiner et al requires that the antiabnormal type prion monoclonal antibody originate from an animal immunized with an immunogen including a peptide consisting essentially of a plurality of regions in said abnormal type prion. Thus, Prusiner et al fails to suggest or disclose such a monoclonal antibody and therefore, there exists no anticipation.

The examiner has considered applicants' argument, but does not find it persuasive. The rejection is maintained for the reasons put forth in the original rejection. The claims are drawn

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to a monoclonal antibody which binds with abnormal type prion but does not substantially bind with normal type prion. In the absence of evidence to the contrary, the process by which the antibody is produced does not impart any criticality to the product's binding characteristics. Thus, the monoclonal antibody of Prusiner et al does anticipate applicants' antibody and the packaging of all necessary reagents for the immunoassay taught by Prusiner et al in a convenient form would have been obvious at the time the invention was made to a person having ordinary skill in the art.

New Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 4, 10, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims depend from rejected claims.

Conclusion

18. Claims 1, 2, 4, 7-16, and 17-20 are finally rejected. Claim 5 appears to be free of the prior art of record.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of

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the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

August 18, 2004